

Rapaflo (Silodosin) and Jalyn (Dutasteride/Tamsulosin) Step Therapy/Prior Authorization Criteria for Alpha Blockers for Benign Prostatic Hypertrophy

Background

Alpha blockers for benign prostatic hypertrophy (BPH) include two non-selective agents (doxazosin and terazosin) and three uroselective agents (Uroxatral, Flomax and Rapaflo). Doxazosin, terazosin, Uroxatral and generic tamsulosin (Flomax) are on the Uniform Formulary. Rapaflo is non-formulary.

DoD's preferred agents for patients who require an uroselective alpha blocker are generic tamsulosin or Uroxatral (alfuzosin), which are similar to Rapaflo in clinical effectiveness and more cost effective than Rapaflo for both DoD and for beneficiaries.

In order to promote use of generic tamsulosin or Uroxatral for those patients who require an uroselective alpha blocker, step therapy/prior authorization requirements apply to Rapaflo. TRICARE coverage for Rapaflo depends on whether you meet step therapy/prior authorization criteria.

Jalyn is a branded combination product containing tamsulosin and the 5-Alpha Reductase Inhibitor dutasteride. It may be used for the same condition (benign prostatic hypertrophy) as tamsulosin and Uroxatral. Jalyn will be available for a \$9 cost share for patients meeting the prior authorization criteria below.

What is Step Therapy?

Step therapy involves prescribing a safe, cost effective medication as the first step in treating a medical condition. The preferred medication is often a generic medication that offers the best overall value in terms of safety, effectiveness, and cost. Non-preferred drugs are only prescribed if the preferred medication is ineffective or poorly tolerated.

Rapaflo will only be approved for first time users after they have tried Uroxatral or generic tamsulosin. Beneficiaries who filled a prescription for either Uroxatral, Flomax or Rapaflo during the last 180 days will not be affected by step therapy requirements and won't have to switch medications.

Patients receiving Uroxatral or Tamsulosin

You will be able to continue to receive Uroxatral at the formulary cost share. Generic tamsulosin, doxazosin and terazosin are also available at the generic cost share.

Patients currently receiving Rapaflo or Jalyn

If you have filled a prescription for Rapaflo or Jalyn through your TRICARE benefit during the previous 180 days, you will be able to continue to receive Rapaflo at a non-formulary (Tier 3) cost share or Jalyn at a formulary cost share.

Patients starting treatment with Rapaflo

You must have tried generic tamsulosin or Uroxatral in the previous 180 days in order for TRICARE to cover a

prescription for Rapaflo, unless you meet prior authorization criteria.

Cost shares for patients starting treatment with Flomax, Rapaflo, or Jalyn

| | Retail network pharmacy (up to a 30-day supply) | Mail order pharmacy (up to a 90-day supply) | Military Treatment Facility |
|--|--|--|--------------------------------|
| Generic tamsulosin, doxazosin or terazosin | Generic cost share applies | \$0 | \$0 |
| Uroxatral | Formulary cost share applies | Formulary cost share applies | \$0 |
| Rapaflo, Jalyn | Must try Uroxatral or Generic Tamsulosin ¹ | | |

Or meet prior authorization criteria (see below)

Prior Authorization Criteria

The following criteria were established by the DoD P&T Committee at their November 2007 meeting. The prior authorization form for these medications is available on the IRICARE Pharmacy Prior Authorization page. The effective date is 16 Apr 2008 (updated Dec 2009 and May 2010 for Rapaflo).

Step Therapy / Prior Authorization Criteria for Jalyn and Rapaflo

TRICARE will NOT cover Jalyn or Rapaflo for new patients—defined as patients who have not filled at least one prescription for an uroselective alpha blocker (Uroxatral, Flomax or Rapaflo) in the previous 180 days at any DoD Pharmacy point of service— UNLESS the patient meets one of the following criteria:

Rapaflo

- 1. The patient has tried tamsulosin or Alfuzosin and had an inadequate response.
- 2. The patient has tried tamsulosin or Alfuzosin and was unable to tolerate it due to adverse effects.
- 3. Treatment with tamsulosin or Alfuzosin is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency).
- 4. The patient has swallowing difficulties and requires an alpha blocker that can be crushed (Rapaflo).

Jalyn

- 1. The patient has tried tamsulosin or Alfuzosin and had an inadequate response AND requires therapy with both an alpha-1 blocker (A1B) and a 5-alpha reductase inhibitor (5-ARI).
- 2. The patient has tried tamsulosin or Alfuzosin and was unable to tolerate it due to adverse effects AND requires therapy with both an alpha-1 blocker (A1B) and a 5-alpha reductase inhibitor (5-ARI).
- Treatment with tamsulosin or Alfuzosin is contraindicated (e.g., hypersensitivity; moderate to severe hepatic insufficiency) AND requires therapy with both an alpha-1 blocker (A1B) and a 5-alpha reductase inhibitor (5-ARI).
- 4. The patient requires therapy with both an alpha-1 blocker (A1B) and a 5-alpha reductase inhibitor (5-ARI) AND requires a fixed-dose combination due to, for example, swallowing difficulties.

Criteria approved through the Uniform Formulary decision-making process (13 Feb 2008, 21 Oct 2009, 13 May 2010, 11 May 2011).

